

REMARKS/ARGUMENTS

Claims 1-18 have been canceled. New Claims 19-44 are active in the case.

Reconsideration is respectfully requested.

The present invention relates to a process of preparing an aqueous suspension of drug particles to be administered to a subject by inhalation.

Claim Amendments

Original Claims 1-10 have been canceled in favor of new Claims 19-29. New Claim 19 in particular is supported by original Claim 1 limited to steps (a) and (b) and Figure 1. New Claim 20 is supported by step (c) of Claim 1. New Claim 30 is supported by original Claim 1.

New Claims 31-34 are supported by the text of the application at page 7, lines 11-13; page 6, lines 19-23; and page 8, lines 1-3.

Original Claims 11-18 support new Claims 35-41, 43 and 44. New Claim 42 is supported by page 9, lines 25-28 of the text.

No new matter has been introduced into the claims by the presentation of the new claims. Entry of the new claims into the record is respectfully requested.

Claim Objections

The objection to Claims 4-14, 17 and 18 is obviated by the cancellation of these claims in favor of new Claims 23-30 and 41, 43 and 44 in which multiple dependency has been eliminated. Entry of the new claims into the record is respectfully requested.

Claim Rejections, 35 USC 112

The presentation of new Claim 19 in place of Claim 1 overcomes the issues raised by the Examiner on page 2 of the Office Action. Accordingly, the claims which depend upon Claim 19 are not indefinite. Entry of the new Claim 19 into the record is respectfully requested.

Prior Art Rejection, 35 USC 102

Claims 1-18 stand rejected based on 35 USC 102 as anticipated by Bernini et al, WO 00/25746. This ground of rejection is respectfully traversed.

As applicants have stated in their specification on page 4, Example 2 of the '746 reference discloses the preparation of an aqueous suspension on the pilot plant scale in which sterilized and micronized BDP is placed in suspension firstly by magnetic stirring and then by turbine stirring at 2600 rpm. However, when this process is applied on the industrial scale, the processing times for achieving homogenization are long, and the dispersions obtained do not have satisfactory homogeneity. This is not the process of the present invention where no magnetic stirring of the particle containing suspension is conducted and where a vacuum is applied to the turboemulsifier to form the dispersion of the active ingredient in the aqueous medium.

Example 2 of the present text is an embodiment of the process of the present invention in which an active ingredient in an aqueous solution in a turboemulsifier is dispersed as a vacuum is applied. The results of this experiment and that of Example 2 of the '746 reference are presented in Example 3 of the present specification and in Figure 2 of the application. Table 2 presents the particle-size characteristics of the suspensions of the two Example 2s. In the table, Preparation 1 shows the results obtained from Example 2 of the present specification, while Preparation 2 shows the results obtained from Example 2 of the

cited '746 reference. The data in the table clearly show the superior Feret diameter and median volumetric diameters (with and without sonication) of Preparation 1 in contrast to the product of Example 2 of the '746 reference identified in Table 2 as Preparation 2. Figure 2 shows the particle distribution frequency according to size ranges, expressed by the Feret diameter, of the product of Example 2 of the invention and of the product of Example 2 of the '746 reference. The results shows that the process of the invention produces finer particles with a narrower and more homogenous particle-size distribution. Clearly, the present process is patentably distinguished over that of the '746 reference. Withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 1-10 stand rejected based on the ground of non-statutory obviousness-type double patenting over Claims 2-9 and 13 of U.S. Patent 6,464,956. This ground of rejection is respectfully traversed.

The cited US patent is the US equivalent of the '746 WO patent discussed in detail above. Since it has been demonstrated that the present invention as claimed is patentably distinguished over the disclosure of '746, it is clear that the invention as claimed is patentably distinguished over Claims 2-9 and 13 of the patent. The claims of the US patent do not suggest to one of skill in the art of conducting a high speed dispersion of active particles in an aqueous medium in a turboemulsifier as a vacuum is applied to the device. Accordingly, withdrawal of the rejection is respectfully requested.

IDS

Applicants enclose an IDS with attached Form 1449. The document attached to the IDS is not prior art per se, but rather is simply a copy of applicant's reply to the Office Action

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of March 18, 2005 in the corresponding European case. Accordingly, a fee for petition and consideration of the IDS is not enclosed, because new prior art is not being reported. If the Office disagrees, a charge to the undersigned account with the Patent Office may be charged.

It is now believed that the application is in proper condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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